

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V.,
JANSSEN, L.P., and
SYNAPTECH, INC.,

Plaintiffs,

v.

ALPHAPHARM PTY., LTD.

Defendant.

Civ. Action No. 05-420 (KAJ)

**JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P.,
AND SYNAPTECH, INC.’s REPLY TO COUNTERCLAIMS**

Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P.
(collectively, “Janssen”), and Synaptech, Inc. (collectively, “Plaintiffs”), by their
attorneys, reply to the Counterclaims of Alphapharm Pty., Ltd. (“Alphapharm”), as
follows:

1. Paragraphs 1-34 of Alphapharm’s Answer are not part of the Counterclaims and require no response by Plaintiffs.
2. In response to Counterclaim Paragraph 1, Plaintiffs admit that Alphapharm has filed counterclaims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but deny that Alphapharm has stated a claim upon which relief may be granted.
3. Plaintiffs admit the allegations of Counterclaim Paragraph 2.
4. Plaintiffs admit the allegations of Counterclaim Paragraph 3.

5. In response to Counterclaim Paragraph 4, Plaintiffs admit that there is an actual and justiciable controversy between the parties as to the infringement and validity of the '318 patent. Plaintiffs deny the remaining allegations of Counterclaim Paragraph 4.

6. In response to Counterclaim Paragraph 5, Plaintiffs admit that Janssen, L.P. is the holder of approved NDA No. 21-169 for galantamine hydrobromide tablets in doses of Eq. 4 mg base, 8mg base, and 12 mg base. Plaintiffs deny the remaining allegations of Counterclaim Paragraph 5.

7. In response to Counterclaim Paragraph 6, Plaintiffs admit that Janssen, L.P. or its predecessor caused the '318 patent to be listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as a patent which claims the drug for which Janssen, L.P. or its predecessor submitted NDA No. 21-169 or which claims a method of using such drug. Plaintiffs further admit that Synaptech, Inc. is the owner of the '318 patent and that Janssen is the exclusive licensee. Plaintiffs deny the remaining allegations of Counterclaim Paragraph 6.

8. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Counterclaim Paragraph 7, and on that basis deny the allegations set forth therein. Plaintiffs state that Alphapharm has asserted that "Alphapharm submitted its ANDA No. 77-603 to obtain FDA approval to engage in the commercial manufacture, use and sale of galantamine hydrobromide tablets, prior to the expiration of the '318 patent."

9. In response to Counterclaim Paragraph 8, Plaintiffs admit that notice letters dated May 11, 2005 were received, which contain Alphapharm's assertions concerning the '318 patent. Plaintiffs deny the remaining allegations of Counterclaim Paragraph 8.

10. Plaintiffs admit the allegations of Counterclaim Paragraph 9.

11. Plaintiffs reply that they are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Counterclaim Paragraph 10, and on that basis deny the allegations set forth therein.

12. In response to Counterclaim Paragraph 11, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

13. Plaintiffs deny the allegations of Counterclaim Paragraph 12.

14. In response to Counterclaim Paragraph 13, Plaintiffs reallege their responses contained in the preceding paragraphs as if fully set forth herein.

15. Plaintiffs deny the allegations of Counterclaim Paragraph 14.

16. Plaintiffs deny that Alphapharm is entitled to any of the relief it has requested.

17. Any allegation not specifically admitted is denied.

Affirmative Defense

18. Alphapharm's Counterclaims are barred in whole or in part because they fail to state a cause of action upon which relief may be granted.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

- A. A judgment dismissing with prejudice Alphapharm's Counterclaims and each and every Prayer for Relief contained therein;
- B. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;
- C. An award of costs and expenses of Plaintiffs in defending these Counterclaims;
- D. A judgment including each and every Prayer for Relief sought by Plaintiffs in the Complaint; and
- E. Such further and other relief as this Court determines to be just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (Delaware Bar No. 2114)
John G. Day (Delaware Bar No. 2403)
222 Delaware Avenue
17th Floor
P.O. Box 1150
Wilmington, DE 19899
Tel: 302-654-1888
Fax: 302-654-2067
sbalick@ashby-geddes.com
jday@ashby-geddes.com

Attorneys for Plaintiffs

Of Counsel:

George F. Pappas
Roderick R. McKelvie
Christopher N. Sipes
Jeffrey B. Elikan
Laura H. McNeill
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Tel: 202-662-6000
Fax: 202-662-6291

Steven P. Berman
Office of General Counsel
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Tel: 732-524-2805
Fax: 732-524-5866

DATED: August 31, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on the 31st August, 2005, the attached **JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., AND SYNAPTECH, INC.'S REPLY TO COUNTERCLAIMS** was served upon the below-named counsel of record at the address and in the manner indicated:

Frederick L. Cottrell, III, Esquire
Richards, Layton & Finger
One Rodney Square
P.O. Box 551
Wilmington, DE 19899

HAND DELIVERY

Alan H. Bernstein, Esquire
Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd.
1635 Market Street, 12th Floor
Philadelphia, PA 19103

VIA FEDERAL EXPRESS

/s/ Steven J. Balick

Steven J. Balick